REMARKS

A final Office action was mailed in the above-captioned application on January 22, 2006. Claims 6, 8-12, 21, 24, 29, 30 and 34-36 were pending in the application. Claims 6, 8-12, 21, 24, 29, 30 and 34-36 were rejected. This Amendment and Remarks document is submitted in response to said Office action.

Claims 34-36

Claims 34-36 were not specifically rejected or allowed in the Office action; however, claims 34 and 35 appear to fall in the range of allowable subject matter as described in the Office action. Claims 34 and 35 have therefore been cancelled and the limitations of Claims 34 and 35 have been introduced into the respective independent claims 6 and 12.

Additionally, Claim 36 has been cancelled and the limitation of Claim 36 has been introduced into independent claim 21.

The Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 6, 8-11, 21, 24, 29-31 and 33 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The first paragraph of § 112 requires that a patent application be written so as to "enable any person skilled in the art to which it pertains . . . to make and use the same." A specification is presumed to be enabling absent "a reason to doubt the objective truth of the statements contained therein." *In re Marzocchi*, 169 USPQ 367, 369 (C.C.P.A 1971). Further, a specification "may be enabling even though some experimentation is necessary," *United States v. Teletronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), so long as the amount of experimentation required is not "undue experimentation." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The test is whether the specification "provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Further, it is a tenet of patent law that an applicant need not teach what the skilled artisan already knows.

Instead, it is preferred that an applicant "omit what is known in the art." *Hybritech Inc. v. Monoclonal Antibodies*, 231 USPQ 81, 94 (Fed. Cir. 1986).

Specifically, the rejection states that the claims are drawn to methods of determining "any" BMD-independent fracture susceptibility, and methods of formulating "any" treatment regime. Applicants do not acquiesce in this rejection; however, in the interest of expediting prosecution, amendments have been made to address these concerns. Applicants reserve the right to pursue cancelled subject matter in a continuing application.

Claims 6, 12, 21, and 24 have been amended replace the recitation "BMD-independent fracture" with "vertebral BMD-independent fracture."

With regard to Claim 21, the rejection further states that is it unclear and unpredictable if any treatment regimen decreases the risk of bone fracture, and the steps to recommend a treatment regimen are not provided in the specification. Applicants disagree with this analysis. The rejection suggests that Claim 21 is directed to a selection from a range of treatments in patients who need some sort of treatment. Claim 21, however, is directed to a selection of people who could benefit from treatment or intervention as compared to those who would not. In other words, the genotyping detects people who are at risk of a well-known type of fracture and would therefore be prescribed treatments which are known to reduce that type of fracture risk. In the interest of expediting prosecution, Claim 21 has been amended to address the concerns in the rejection. Claim 21 has been amended to recite that the method is a method of recommending a treatment. The word "regimen" has been deleted from Claim 21. Claim 21 now recites that the treatment comprises at least one treatment selected from the group consisting of modifications to lifestyle, regular exercise, changes in diet and administration of a pharmaceutical preparation effective to prevent or reduce the risk of vertebral BMD-independent fracture. Support for this amendment can be found at page 15, line 15-26.

Claim 21 is a method of determining susceptibility to vertebral BMD-independent fracture in part by genotypic analysis (i.e., determining the presence of certain haplotypes). This method has been described in the specification. Claim 21 recites that the treatment regimen is effective to decrease the risk of vertebral BMD-independent fracture. Since a certain genotype (i.e., both haplotypes) is associated with an increased susceptibility to vertebral BMD-independent fracture, it is clear and predictable to recommend treatment known to reduce the susceptibility of bone fracture, reduce bone loss, and the like.

Claim 21 recites the steps of 1) genotypic analysis, that is, analyzing nucleic acid molecules of the subject to determine whether both said haplotypes are present in said subject; and 2) recommending a treatment when both said haplotypes are present in said subject. These steps are supported by the specification. The specification supports prescribing (recommending) certain treatments at page 15, lines 15-26. The recommendations are those treatments that reduce the susceptibility of bone fracture (lines 16-17) reduce bone loss (line 24), and the like (lines 23-24).

Applicants submit the claim is clear and predictable as written and that there are no further "necessary steps" in recommending a treatment. In the interest of expediting prosecution, however, Claim 21 has been further amended to recite that treatment comprises at least one treatment selected from the group consisting of modifications to lifestyle, regular exercise, changes in diet and administration of a pharmaceutical preparation effective to prevent or reduce the risk of vertebral BMD-independent fracture.

In summary, Claim 21 now refers to a method of recommending a treatment to decrease the risk of vertebral bone mineral density (BMD)-independent fractures based on a genotypic analysis and the resulting risk factor, and specifies that the treatment comprises at least one treatment selected from the group consisting of modifications to lifestyle, regular exercise, changes in diet and administration of a pharmaceutical preparation effective to prevent or reduce the risk of vertebral BMD-independent fracture.

Applicants submit that the claims, as amended, are fully enabled by the specification, and respectfully requests reconsideration of the rejection under 35 U.S.C. § 112, first paragraph.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

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